

Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

New Substances Notification 20701: Formaldehyde, polymer with 2-phenoxyethanol and α -phenyl- ω -hydroxypoly(oxy-1,2-alkanediyl), dihydrogen phosphate 2-phenoxyalkyl hydrogen phosphate, metal salt (Confidential Accession No. 19532-0)

Regulatory decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 83 of the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance and have determined that it is not anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

Substance identity

The notified polymer is formaldehyde, polymer with 2-phenoxyethanol and α -phenyl- ω -hydroxypoly(oxy-1,2-alkanediyl), dihydrogen phosphate 2-phenoxyalkyl hydrogen phosphate, metal salt (Confidential Accession No. 19532-0). The substance does not meet the Reduced Regulatory Requirements criteria according to the *New Substances Notification Regulations (Chemicals and Polymers)* because it contains phosphorus above 0.2% by weight.

Notified and potential uses

The substance is proposed to be imported into Canada in quantities greater than 10 000 kg/yr for the notified use as an additive in cement. No other uses are anticipated in Canada.

Environmental fate and behaviour

Based on its physical and chemical properties, if the substance is released to the environment, it will tend to partition to water. The substance is not expected to be persistent in water based on its expected moderate biodegradation (30-60% over 28 days). The substance is not expected to bioaccumulate based on its high molecular weight, which will limit its ability to cross biological membranes.

Environmental risk assessment

Based on the available hazard information, the substance is expected to have low acute toxicity to fish and aquatic invertebrates (median lethal concentration and median effective concentration >100 mg/L), and low to moderate chronic toxicity to algae (10% effective concentration (EC_{10}) >0.1 mg/L). Using the EC_{10} from the most sensitive organism (algae) and by applying an assessment factor of 4 to account for species sensitivity variation and mode of action, the predicted no-effect concentration (PNEC) was calculated to be in the range of 1000-10 000 μ g/L, which was used to estimate the ecological risk.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activities is expected to be mainly from transport vessels cleaning and formulation from release of the

substance to water resulting in predicted environmental concentrations (PEC) in the range of 1-100 µg/L and 0.1-1 µg/L, respectively. For potential activities such as manufacturing, environmental exposure is expected to be mainly from release of the substance to water resulting in a PEC in the range of 10-100 µg/L.

Comparing the PEC with the PNEC, the ratio is less than 1. This, along with other lines of evidence including environmental fate, hazard, and exposure, indicates that the substance is unlikely to cause ecological harm in Canada.

Human health risk assessment

Based on the available hazard information, the substance has a low acute toxicity by the oral route (median lethal dose >2000 mg/kg body weight). The substance does not contain structural features associated with adverse human health effects.

When the notified substance is used as an additive in cement in an industrial or commercial setting, exposure of the general population is not expected as the substance will be encapsulated within a stable matrix once the product is set and will be unavailable for uptake. When the notified substance is used as an additive for cement products available for use by Do-It-Yourself consumers, users may come into contact with products containing the substance; however, direct exposure is expected to be mainly by incidental contact with the skin at low levels. Once the cement has set, the substance will be encapsulated within a stable matrix and will be unavailable for uptake. Indirect exposure of the general population from environmental media such as drinking water is expected to be at low levels given the low potential for environmental release and the biodegradation of the substance in the environment. No potential uses that could significantly increase human health risks compared to the notified use were identified.

Based on the low toxicity, low potential for exposure and the absence of structural features associated with adverse human health effects, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

The assumptions made in the assessment are considered to be adequately protective for the general population as well as for subpopulations who may be more susceptible or highly exposed.

Assessment conclusion

When the substance is used as notified or for other identified potential activities, it is not expected to be harmful to human health or the environment according to the criteria under section 64 of the Act.

A conclusion under CEPA, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or *Hazardous Products Regulations* for products intended for the workplace.